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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0822; FRL-9939-52]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on quinoa grain, ti leaves, ti roots, and modifies the existing tolerances for the stone fruit group 12 and tree nut group 14 to read "stone fruit group 12-12" and "tree nut group 14-12, except pistachio" respectively. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0822, is available at <http://www.regulations.gov> or at the Office of Pesticide

Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0822 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0822, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 4, 2015 (80 FR 11611) (FRL-9922-68), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8319) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of azoxystrobin (methyl (E)-2-{2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) in or on the raw agricultural commodities ti palm, leaves at 50 parts per million (ppm); ti palm, roots at 0.5 ppm; fruit, stone, group 12-12 at 2.0 ppm; and nut, tree, group 14-12 at 0.02 ppm. Upon the approval of the aforementioned tolerances, the petitioner requested to remove the established tolerances for azoxystrobin in or on the raw agricultural commodities fruit, stone, group 12 at 1.5 ppm; and nut, tree, group 14 at 0.02 ppm. That document referenced a summary of the petition prepared

by Syngenta Crop Protection, the registrant, which is available in the docket, <http://www.regulations.gov>. EPA received two comments in response to the March 4, 2015 Notice of Filing that simply said “Good.”

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA amended the initial notice of filing for pesticide petition (PP 4E8319), including the commodity quinoa grain at 3.0 ppm in addition to the commodities originally requested and listed above. Comments were received to the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

EPA has modified the tolerance for the tree nut group 14-12 to exclude pistachio. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with FFDCA section 408(b)(2), for tolerances for residues of azoxystrobin in or on quinoa grain, ti palm leaves, ti palm roots, the stone fruit group 12-12, and the tree nut group 14-12. As discussed below, EPA is relying upon the findings in the preamble to the rule published in the **Federal Register** May 1, 2015 (80 FR 24824) (FRL-9926-24) establishing tolerances for azoxystrobin and supporting risk assessments to establish and modify these tolerances.

On May 1, 2015, EPA published a final rule establishing tolerances for residues of azoxystrobin in or on coffee, green bean; pear, Asian; and tea, dried based on the Agency's conclusion that aggregate exposure to azoxystrobin is safe for the general population, including infants and children. In addition to the tolerances listed above, EPA also considered the following uses in the risk assessments that supported the May 1, 2015 final rule: Ti palm leaves, ti palm roots, the stone fruit group 12-12, and the tree nut group 14-12 and also separately evaluated the request to establish a tolerance in or on quinoa grain.

Since the publication of the May 1, 2015 final rule, the toxicity profile of azoxystrobin has not changed, and the risk assessments that supported the establishment of those azoxystrobin tolerances published in the May 1, 2015 **Federal Register** remain valid. Those risk assessments also support the establishment of the tolerances that are the subject of this action. The Agency also evaluated the request to establish a tolerance in or on quinoa grain at 3.0 ppm and concluded that the aggregate exposure and risks would not increase as a result of the proposed use on quinoa and are the same as those estimated in the May 1 final rule. Therefore, EPA is relying on those risk assessments in order to establish the new tolerances. For a detailed discussion of the aggregate risk assessments and determination of safety for the proposed

tolerances, please refer to the May 1, 2015 **Federal Register** document and its supporting documents, available at <http://www.regulations.gov>. EPA relies upon those supporting risk assessments and the findings made in the **Federal Register** document in support of this rule.

Based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to azoxystrobin residues. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the May 1, 2015 **Federal Register** action, as well as the new azoxystrobin tolerances can be found at <http://www.regulations.gov> in the documents entitled: "Azoxystrobin. Human Health Aggregate Risk Assessment for Permanent Tolerances on Imported Asian Pear, Imported Tea, and Imported Coffee; Establishment of Permanent Tolerances on Ti Palm and for Crop Group Conversions for Stone Fruits Group 12-12 and Tree Nut Group 14-12 Crop Groups" and "Azoxystrobin. Addendum to Human Health Aggregate Risk Assessment D423691 and D418374, Dated 4/7/2015, to Support a New Use on Quinoa." The documents may be found in docket ID number EPA-HQ-OPP-2014-0822.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with a nitrogenphosphorus detector (GC/NPD) method, RAM 243/04) is available to enforce the tolerance expression for residues of azoxystrobin and its Z-isomer in crop commodities. This method (designated RAM 243, dated 5/15/98) has been submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM), Volume II.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for quinoa grain or ti palm leaves or roots.

The Codex has established an MRL for stone fruit at 2 milligram/kilogram (mg/kg), which is harmonized with the U.S. tolerance of 2 ppm.

The Codex has established an MRL of 0.01 mg/kg for tree nuts. The US crop group tolerance is based on a residue definition of azoxystrobin plus the Z-isomer (R230310). Residues were < 0.01 ppm for each component in the almond and pecan trials. Therefore, the tolerance estimate is 0.02 ppm, the sum of the components. The Codex residue definition is parent only,

which support the 0.01 mg/kg MRL. The US tolerance cannot be harmonized with Codex at this time.

C. Response to Comments

Four comments were received in response to the October 21, 2015 notice of filing. The first comment asserted that no residues should be allowed and that the pesticide should not be approved for sale or use. The second stated that pesticides are “causing normally healthy people to have serious life treating (sic) health issues and is making many Americans overweight” and the commenter did not want their food to have pesticide residues. The third commenter stated that they were very allergic to any chemical and demanded that all chemical treatments must be rejected and stopped. The Agency understands the commenters’ concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The comments appear to be directed at the underlying statute and not EPA’s implementation of it; the citizens have made no contention that EPA has acted in violation of the statutory framework.

The fourth comment was from the Center for Biological Diversity and concerned endangered species; specifically stating that EPA cannot approve this new use prior to completion of consultations with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (“the Services”). This comment is not relevant to the Agency’s evaluation of safety of the azoxystrobin tolerances; section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

D. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance for “Nut, tree, group 14-12” is being modified to read “Nut, tree, group 14-12, except pistachio” because an existing tolerance for pistachio exists at a higher level (0.50 ppm). In addition, although the petition requested tolerances for ti palm leaves and roots, EPA is establishing tolerances for “ti, leaves” and “ti, roots” to be consistent with its food and feed commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin (methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) in or on the raw agricultural commodities quinoa, grain at 3.0 ppm; ti, leaves at 50 ppm; and ti, roots at 0.5 ppm. Additionally, the existing tolerance for “fruit, stone, group 12” is modified to read “fruit, stone, group 12-12” and to increase the tolerance level from 1.5 ppm to 2.0 ppm. Finally, the existing tolerance for “nut, tree, group 14” is modified to read “nut, tree, group 14–12, except pistachio.”

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not

contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 2, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.507:

a. Add alphabetically the commodities to the table in paragraph (a)(1).

b. Revise the commodities “fruit, stone, group 12” and “nut, tree, group 14” in paragraph (a)(1).

The additions and revisions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million

Fruit, stone, group 12-12	2.0

Nut, tree, group 14-12, except pistachio	0.02

Quinoa, grain	3.0

Ti, leaves	50.0
Ti, roots	0.5

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[FR Doc. 2015-31053 Filed: 12/8/2015 8:45 am; Publication Date: 12/9/2015]